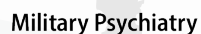


## WRAIR'S INVESTIGATOR'S DISPATCH



## WRAIR PROTECTS YOUR SIX

CENTER FOR MILITARY PSYCHIATRY AND NEUROSCIENCE



CENTER FOR INFECTIOUS DISEASE RESEARCH



## WALTER REED ARMY INSTITUTE OF RESEARCH'S MISSION

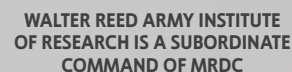
Discover, design, and develop solutions for military relevant infectious disease and brain health threats through innovative research protecting and optimizing warfighter lethality.

**LIKE AND FOLLOW WRAIR**



## PROMOTED HASHTAGS

#ForgeTheFuture #SoldierHealth



The opinions or assertions contained herein are the private views of the author and are not to be construed as official.



LETTER FROM COL DEYDRE TEYHEN,  
COMMANDER OF THE WALTER REED ARMY INSTITUTE OF RESEARCH

General Stephen Townsend, former Commanding General of the U.S. Army Training and Doctrine Command, opened his preface to a pamphlet on multi-domain operations by saying, “one of our duties as Army professionals is to think deeply and clearly about the problem of armed conflict in the future so that we can build and prepare our Army to deter that conflict and, if necessary, fight and win it.”

Though future conflicts, spanning multiple domains on land, sea, air, space and cyber, will require significant technical advancements including communications, precision fires and other enabling capabilities, the U.S. Soldier remains the nation’s top weapons system and the most critical component to winning its wars.

Operating since 1893, WRAIR has been on the front line of protecting and enhancing Soldier readiness and lethality, particularly in the areas of brain health and infectious disease. Though WRAIR’s work maintains Soldier health, its products also have important civilian applications, saving countless lives around the world.

To stay on the front line, 2019 was a time of change. WRAIR welcomed researchers from the now-deactivated U.S. Army Center for Environmental Health Researcher and continued its internal reorganization, including operationalizing the new Center for Enabling Capabilities to organize and unite the unique competencies that allow WRAIR to conduct research at the velocity of relevance.

Our research focus also shifted to ensure that WRAIR’s global research network, including the Center for Infectious Disease Research, the Center for Military Psychiatry and Neuroscience and medical research directorates in Africa (U.S. Army Medical Research Directorate-Africa), Southeast Asia (U.S. Army Medical Directorate-Armed Forces Research Institute of Medical Sciences), the Republic of Georgia (U.S. Army Medical Research Directorate-Georgia) and Washington State (U.S. Army Medical Research Directorate-West), meet the needs of the far-forward Soldier operating in the multi-domain environment.

Thank you for joining us as we highlight the accomplishments of WRAIR’s approximately 2,700 Soldiers, civilians and contractors.



TABLE OF CONTENTS

COL DEYDRE TEYHEN LETTER\_\_\_\_\_PG 2 – 3

EMERGING INFECTIOUS DISEASE\_\_\_\_\_PG 4

DISEASE IN URBAN ENVIRONMENTS\_\_\_\_\_PG 5

DIS-INTEGRATING DEPLOYMENT-  
RELATE INFECTIOUS DISEASES\_\_\_\_\_PG 6 – 7

PROLONGED FIELD CARE  
IMPLICATIONS\_\_\_\_\_PG 8 – 9

INFECTIOUS DISEASES  
WITH HIGH COSTS FOR THE MHS\_\_\_\_\_PG 10 – 11

BATTLEFIELD RESILIENCE:  
FORGING SOCIAL COHESION\_\_\_\_\_PG 12

BLAST, BRAIN INJURIES, AND  
NEUROPROTECTION\_\_\_\_\_PG 13

FAR-FORWARD BEHAVIORAL  
HEALTH\_\_\_\_\_PG 14

COMPREHENSIVE FATIGUE  
MANAGEMENT\_\_\_\_\_PG 15

WRAIR’S OCONUS  
ACCOMPLISHMENTS \_\_\_\_\_PG 16 – 17

THE BUSINESS OF SCIENCE\_\_\_\_\_PG 18 – 19

PUBLICATIONS\_\_\_\_\_PG 20 – 35



# EMERGING INFECTIOUS DISEASE

Emerging infectious disease (EID) can threaten political and economic stability, overwhelm partner capacity, and jeopardize a calibrated force posture, endangering compete phase activities as well as gains consolidation during the re-compete phase of multi-domain operations (MDO). Infectious disease can emerge in dense, urban, and remote environments, threatening operations during the penetrate, dis-integrate, and exploit phases of MDO. WRAIR's historic experience, extensive capabilities, and international research infrastructure allow its scientists to quickly develop countermeasures against EID threats.



## FIRST-IN-HUMAN TRIAL FOR MARBURG VACCINE

The WRAIR Clinical Trials Center, in collaboration with scientists at the National Institutes of Health's Vaccine Research Center, finished a critical first-in-human Marburg vaccine Phase 1 clinical trial in 2019. Marburg virus disease is similar to Ebola in its clinical symptoms, potentially with a higher mortality rate--during a 2017 outbreak, 67% of cases resulted in death. As Marburg virus disease outbreaks intermittently affect sub-Saharan Africa, they constitute a severe threat to global health.

This important vaccine's development timeline was accelerated in part due to the 2017 outbreak in a Uganda where five people were infected and three died; ongoing Marburg outbreaks intermittently affect sub-Saharan Africa and threaten global health security. A similar Ebola vaccine developed by the VRC was tested in 2016-2017 and determined to be safe and immunogenic.

## USAMRD-A COMPLETES EBOLA CLINICAL TRIALS

U.S. Medical Research Directorate-Africa in Nigeria (USAMRD-A/N) successfully completed the RV 456 clinical trial (Ebola vaccine) with a retention rate of 90% at 12 months. Under RV 456, the USAMRD-A/N mil-mil partnership is the only organization in Nigeria to execute phase II product development in the country. U.S. Medical Research Directorate-Africa in Tanzania conducted joint investigation on the safety and immunogenicity of two prophylactic Ebola vaccine regimens in a Phase II clinical trial. The investigations are now in the data analysis phase and will contribute towards obtaining regulatory clearance for the Ebola vaccines clearance for becoming available to the general public.



## EBOLA VACCINE RECEIVES FDA APPROVAL

WRAIR conducted a series of nonclinical and clinical studies on the Ebola virus vaccine Ervebo, approved by the FDA in December, 2019, against the Zaire strain.

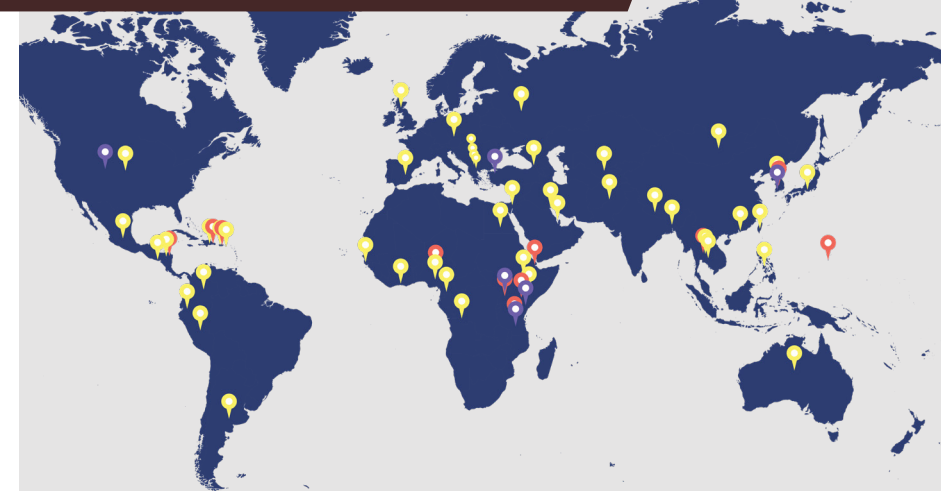
## FIRST-EVER CLINICAL TRIAL OF A MERS-CoV VACCINE

The Emerging Infectious Diseases Branch, in partnership with industry, successfully completed and published the findings from the first-ever clinical trial of a Middle East respiratory syndrome (MERS-CoV) vaccine candidate and the third-ever trial of a coronavirus vaccine candidate. The findings were published in The Lancet Infectious Diseases in September, 2019. Plans are currently underway to test the product South Korea and at a WRAIR-developed site in the Middle East, locations where large MERS-CoV outbreaks have occurred.

# INFECTIOUS DISEASES IN DENSE URBAN, SUBTERRANEAN ENVIRONMENTS

As war disrupts sewage, clean water, and other infrastructure in dense, urban environments, novel disease threats will emerge, threatening inadequately protected Warfighters.

## TRACKING THE NEXT VIRAL THREAT



📍 = Serosurveillance   📍 = Genomic surveillance   📍 = Vector pathogen discovery

The ability of influenza and other respiratory viruses to rapidly diffuse through crowded groups becomes especially relevant in military settings, where the virus can cause sudden illness in densely populated barracks and bases, rendering Soldiers incapable of performing duties. In collaboration with the University of Maryland, we surveil and investigate influenza and coronavirus spread in crowded dormitory settings, which are directly comparable to military barracks environments. Here, we are developing a genomic approach for precise tracking of contacts and virus spread, as well as investigating the impact of different building ventilation systems on the spread of respiratory pathogens.

In collaboration with U.S. Air Force School of Aerospace Medicine (USAFSAM), we are investigating the genomic epidemiology of adenovirus spread in active duty military and their dependents and monitoring changes that may result in the escape from adenovirus 4 and 7 vaccine. Similarly, with USAFSAM, we are tracking the spread of influenza in the above populations, especially infections in already vaccinated individuals, to investigate and track the emergence and spread of influenza vaccine escape.



**Diarrhea ranked 1<sup>st</sup> among 57** infectious disease threats to the force based on its impact to readiness.

**76%** of Soldiers in OIF and OEF experienced traveler's diarrhea early in their deployment.

## TRAVELAN SHIGELLOSIS CHALLENGE COMPLETED



WRAIR, the Armed Forces Research Institute of Medical Science (an overseas WRAIR research directorate), and the Naval Medical Research Center partnered with Immuron to test Travelan against Shigella, enterotoxigenic Escherichia coli, Vibrio cholerae and Campylobacter jejuni isolates. Travelan is a natural product marketed for the prevention of traveler's diarrhea. In a recent pre-clinical study, Travelan prevented the development of shigellosis in 75% of those receiving therapy.

## PHASE 2B CLINICAL TRIAL FOR SHIGELLA VACCINE

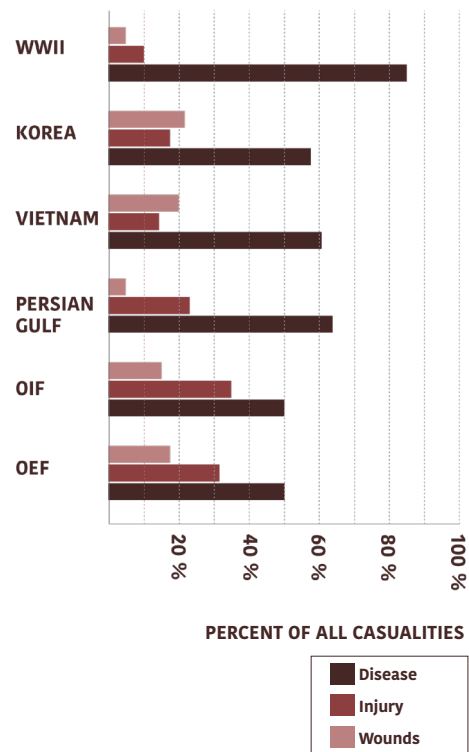
In Western Kenya, Shigella species represent 7%-12% of pathogens detected in acute diarrheal stool. Decreased susceptibility to a range of antibiotics over the past decade has complicated treatment for shigellosis. A Phase 2B clinical trial to determine the efficacy of the Shigella sonnei vaccine, WRSs2, commenced in November, 2019, at Cincinnati Children's Hospital Medical Center. In 2020, the vaccine will be tested in seven sites in Kenya.



# DIS-INTEGRATING DEPLOYMENT-RELATED INFECTIOUS DISEASES

American Soldiers in 140 countries face more than just the threat of enemy action; they also face endemic disease, to which they often do not have any protection from previous exposure. These pathogens are often highly contagious and can spread within a unit, decreasing the efficacy of an individual and their team.

## DISEASE CAUSES MORE CASUALTIES THAN ENEMY ACTION



## COMPLETED PHASE 3 OF DENGUE VACCINE

WRAIR's Viral Disease Branch completes CMI testing for dengue Phase 3 tetravalent vaccine with Takeda Pharmaceutical. This is the first dengue vaccine that utilized cell mediated immunity read-outs as a primary end-point. Takeda, in partnership with the Walter Reed Army Institute of Research, performed early (Phase 1) work on this vaccine candidate showing the robust CMI responses elicited from vaccination. WRAIR Viral Disease Branch was selected as the sole lab for CMI testing of a subset of the 30,000 subject Phase 3 clinical trial.

## FIRST DENGUE VACCINE CHALLENGE STUDY

The Viral Disease Branch secured an important partnership with the University of Maryland Center for Vaccine Development to execute the first dengue vaccine challenge study, where volunteers are safely exposed to dengue infection to test vaccine candidates in field-like settings. This partnership allows the utilization of the WRAIR Clinical Trials Center for vaccine evaluation and a partner in close proximity to execute the challenge phase.



## MALARIAL MOSQUITOES THAT CAN MIGRATE LONG DISTANCES ON HIGH LEVEL WIND CURRENTS IDENTIFIED

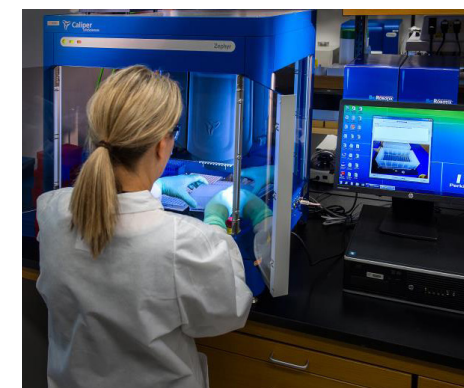
A global team including scientists from the Walter Reed Biosystematics Unit, housed within the Smithsonian National Museum of Natural History and part of the Walter Reed Army Institute of Research, used balloons to capture insects up to 290 meters in the air in the Sahel of Mali. Publishing these findings in Nature, it was demonstrated that previously blood-fed, malaria vectors frequently migrate over hundreds of kilometers, almost certainly spread malaria over such distances. This study has significant implications for malaria prevention and elimination as military entomologists can no longer focus solely on endemic mosquitoes and disease threats.

## COMPLETED THE LARGEST CHMI TRIAL

Building on previous studies conducted at WRAIR, researchers conducted the largest controlled human malaria infection study ever, where 130 healthy adult subjects in five experimental cohorts were safely exposed to malaria to test the RTS,S malaria vaccine. Results from this trial provide valuable information about the vaccine's durability of protection against *Plasmodium falciparum* malaria and suggest that one formulation, the pediatric formulation, may be able to function as a universal formulation. WRAIR, with its partners, was honored with a 2019 Innovating for Impact Award by the Global Health Technologies Coalition for their work with the RTS,S vaccine. Malaria remains one of the most significant infectious disease threats to deployed Service Members.

## DRUG DEVELOPMENT STRATEGY VALIDATED WITH TRIAZINE ANTIMALARIAL COMPOUNDS

Triazine compounds, tested under a selective next generation development effort for drugs to treat and prevent malaria, completed exploratory investigational new drug "Phase 0" testing and received the 2018 Invention of the Year award from USAMRDC. Ultimately, additional non-clinical data collected in spring, 2019, in combination with the results from the Phase 0 trial, supported a decision to terminate all triazine product development efforts. This industry-standard testing paradigm identifies products at the earliest point of non-compliance with the DOD malaria prophylaxis target product profile established by drug researchers; this "quick kill" and portfolio-driven philosophy positions WRAIR to elevate the next candidates in the pipeline and pursue clinical transition far sooner than earlier project-driven approaches.



## NEW DIAGNOSTIC TOOL IMPROVES CHMI PROCESS

In collaboration with MHRP/DLDM, completed validation of a Laboratory Developed PCR assay conducted in a Certified Authorization Professional laboratory targeting an FDA cleared biomarker, 18S rRNA, for the clinical diagnosis of malaria infection in a CHMI trial in naïve adults. Utilization of this assay improves subject safety through earlier diagnosis before symptoms develop and significantly reduced clinical trials cost through elimination of a hotel phase during the malaria challenge.



# ENTOMOLOGY

## SEQUENCED THE GENOMES OF THREE NOVEL MOSQUITOES

Members of the Walter Reed Biosystematics Unit, a part of WRAIR which is housed within the Smithsonian National Museum of Natural History, worked with WRAIR viral diseases researchers to achieve whole genome assemblies for three New World Anopheles mosquito species. To date, WRBU has sequenced 160 whole genomes (including 110 new species). These data allow for forward-facing solutions, identifying specific areas of interest for future vector countermeasure development.

## PUBLISHING THE FIRST GLOBAL MOSQUITO ATLAS IN 35 YEARS

Three authors who either have been or are civilian heads of Walter Reed Biosystematics Unit, a part of WRAIR and housed within the Smithsonian National Museum of Natural History, published a 1,200 page, two-volume book, "Mosquitoes of the World." The book, placed into production by Johns Hopkins Press, covers mosquito biology, systematics and includes a revised taxonomic catalog of mosquitoes including updated current distribution, key works and taxonomic histories for all 3,527 known taxa. The book will be available for purchase June 2020 and will be the only resource of its kind developed within the last 35 years. This resource cements WRBU as an internationally renowned resource for mosquito identification, supporting novel entomological countermeasures to protect the Warfighter.

## WRAIR RESEARCHERS STUDY NEW MOSQUITO BAIT

Entomology researchers published a study in the Journal of Medical Entomology that sodium ascorbate (SA), a naturally-occurring antioxidant compound found in fruits and vegetables, can be added to attractive toxic sugar baits as a vector control tool for mosquitoes and sand flies. Since SA is available commercially in the United States as an additive or supplement, pest and vector control personnel can easily access the compound to enhance several existing vector control technologies.



# PROLONGED FIELD CARE IMPLICATIONS


During near-peer competition, air superiority diminishes, limiting availability to evacuate Soldiers from the point of injury limiting Warfighter sanitation, treatment and resupply capabilities. WRAIR is developing new, far-forward preventive and therapeutic interventions that extend the golden hour to the golden day+, which is required to sustain a lethal and responsive force during large-scale combat operations.



## CHALLENGES OF MULTIDRUG RESISTANCE

The 2019 U.S. Military Infectious Diseases Threat Prioritization Panel named multidrug-resistant bacteria (MDR) as one of the highest tier 1 infectious disease threats, recognizing the high operational risk associated with these pathogens.


As the U.S. military executes its missions worldwide, health care providers in military medical treatment facilities are faced with the dilemma of how to treat infections caused by MDR bacteria, a challenge made worse in operational environments.




**GOLDEN HOUR EVACUATION**  
(OIF/OEF)


52,352<sup>1</sup>

wounded in action






On average 45 - 90 minutes from injury to field hospital




**49%**  
of those wounded had bacteria in their wounds


34%

of combat casualties develop infections during their initial hospitalization





**27%**  
deep infection rate for type III open tibia fractures which may lead to unnecessary amputations



How many infections will we have when we extend to the Golden Day+?



WRAIR's therapeutic bacteriophage

## FIRST BACTERIOPHAGE COCKTAIL VIALED

Due to the sharp rise in pandrug-resistant bacterial pathogens like *Pseudomonas aeruginosa* and *Staphylococcus aureus*, WRAIR's Bacterial Disease Branch (BDB) is pioneering novel treatment strategies such as bacteriophage cocktails. Mixtures of viruses that specifically target bacteria of interest, a cocktail including five bacteriophages was found effective against 75% of *P. aeruginosa* strains circulating worldwide with work ongoing to test it against novel strains. Recently, an emergency Investigative New Drug application for a *P. aeruginosa* phage cocktail developed by BDB and viald by WRAIR's Pilot Bioproduction Facility was submitted to the FDA for use in a patient.

## LEVERAGING STRUCTURE-BASED DRUG DESIGN

WRAIR is the home of the Army's only center for x-ray crystallography for antibiotic discovery. Our state-of-the-art x-ray crystallization allows us to better design countermeasures. WRAIR has developed and is optimizing effective inhibitors against *A. baumannii* & *K. pneumoniae*, two gram-negative bacteria that were often isolated during OIF/OEF. Wound infections by these organisms are often highly resistant to most antibiotics.

## PRE-CLINICAL MODELS DEVELOPED

WRAIR has developed pre-clinical models involving complex polytrauma and infection to understand how wound contamination turns into infection. WRAIR has developed a combat trauma model involving blast to better simulate battlefield-like wounds.

## MRSN RESPONDS TO OVER 50 OUTBREAKS



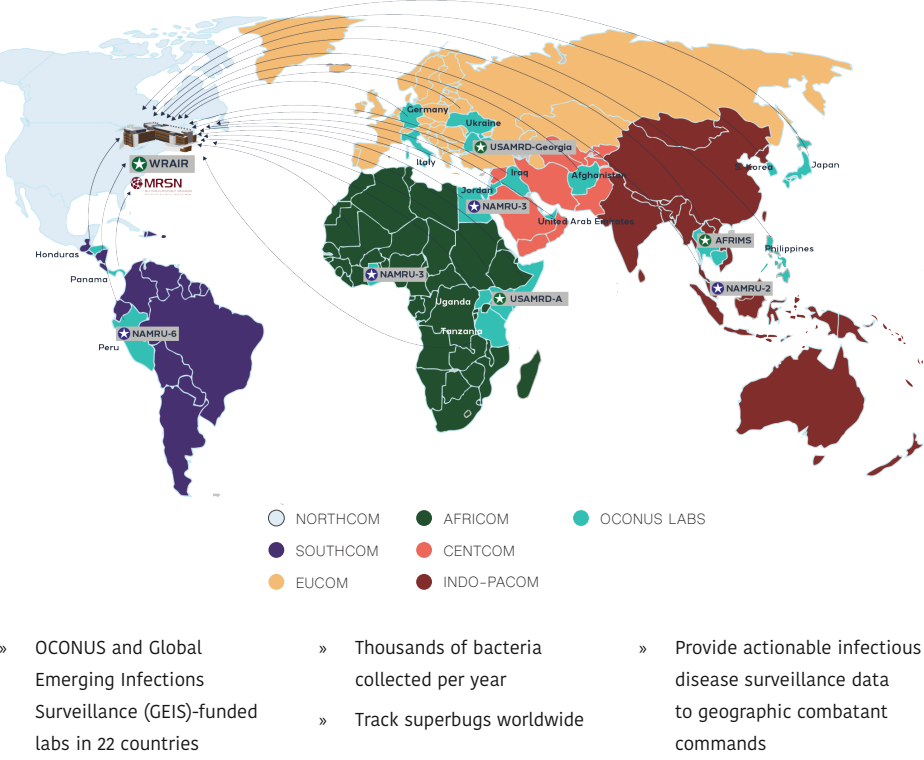
The Multidrug Resistant Organism Repository and Surveillance Network conducted over 50 outbreak investigations within military treatment facilities and remains the DOD's premier laboratory for whole genome sequencing and bioinformatics for multidrug-resistant bacterial pathogens.

Using WGS, the MRSN was able to show that infections in two recruits were not identical to one implicated in a fatal case involving another recruit at Fort Benning, Ga. This information was instrumental in reassuring the Fort Benning Command, and by extension the relatives and family members of new Army recruits, that there was no evidence for an extended hospital-borne outbreak among new recruits at Fort Benning.

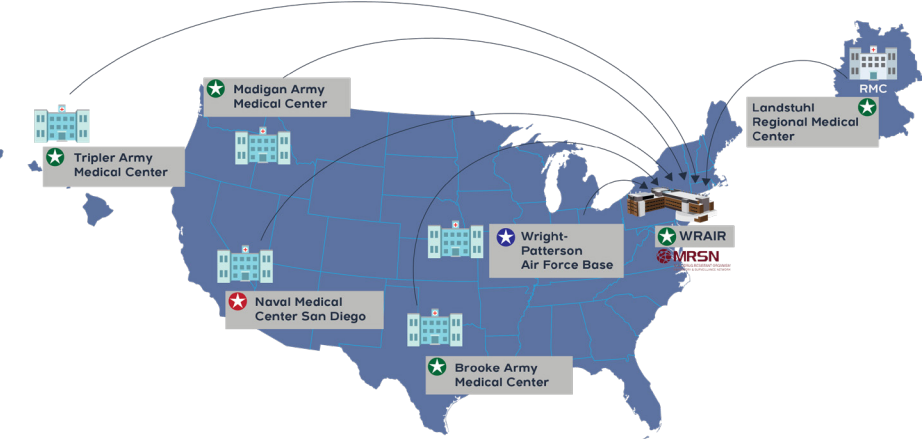
Through close relationships with Air Force microbiologists at Bagram Air Force Base, the MRSN was able to comprehensively identify the presence of high levels of "superbugs" in Afghanistan, leading to increased awareness of this threat throughout the Military Healthcare System and the CENTCOM area of responsibility.

This partnership resulted in direct reports to the geographic combatant commands that culminated in the recent identification of "superbug" colonization in a severely wounded Soldier receiving treatment at Brooke Army Medical Center, San Antonio, Texas. This real-time surveillance is critical in alerting healthcare providers to emerging threats and ensuring appropriate responses to pandrug-resistant bacterial pathogens.

# GLOBAL ANTIBIOTIC RESISTANCE SURVEILLANCE



# DISEASE OUTBREAKS IN THE MILITARY HEALTHCARE SYSTEM



### DISEASE OUTBREAK INVESTIGATIONS IN THE MHS

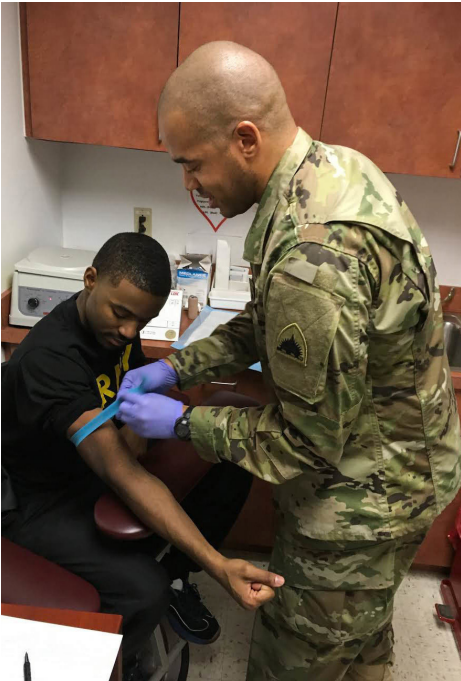
- » Response assistance requested by healthcare professionals
- » 6-8 outbreak investigations per month
- » Turnaround time as short as 48-72 hours

### MTF MDR ORGANISMS SURVEILLANCE

- » All MTfs send MDR bacteria to MRSN in accordance with DOD/DHA policy
- » 500-800 bacterial samples per month received from around the world
- » MRSN performs real-time molecular epidemiology



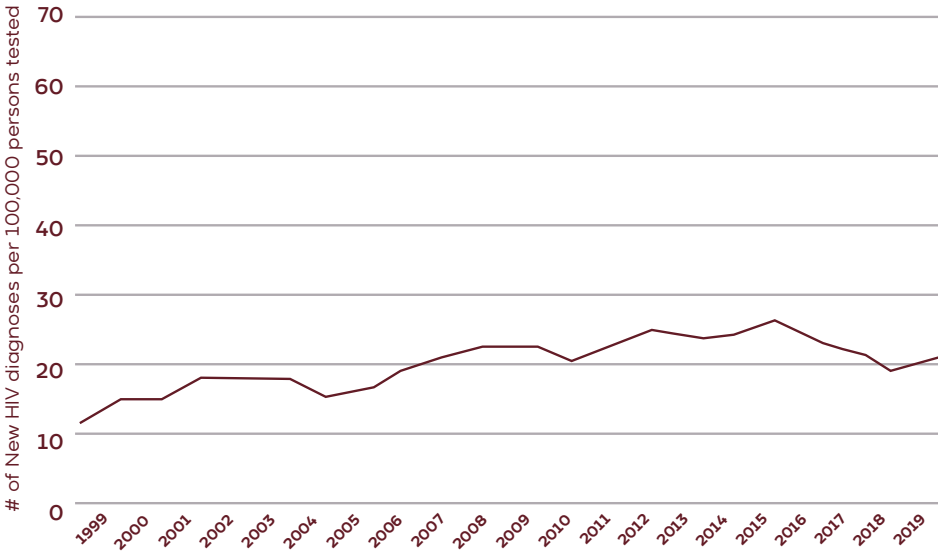
# INFECTIOUS DISEASES WITH HIGH COSTS FOR THE MHS: HIV



The impacts of HIV are widespread and include lowered life expectancy, reduced economic growth and increased health costs. These outcomes ultimately damage social and political cohesion and impede the advancement of global health objectives—posing a risk to national security and the stability of many nation-states.

PEPFAR’s programs help to restore the economic productivity of those infected or affected by HIV and to protect families, communities, and societies from destabilization. Higher levels of PEPFAR funding in a country is associated with greater improvements in World Bank indicators of governance, including: government effectiveness, regulatory quality, and a 31% improvement in the rule of law.

HIV RATES, U.S. ARMED FORCES, 1990-2019



## DOD NUMBERS

**350**  
NEW CASES OF HIV PER YEAR

**\$435,200**  
ESTIMATED LIFETIME COST FOR TREATMENT PER PERSON

**\$150 MILLION**  
ADDITIONAL FINANCIAL BURDEN TO THE DOD/VA ANNUALLY

- » HIV-infected Soldiers can face deployment limitations, compromising unit integrity and their ability to compete in the multi-domain environment.
- » WRAIR’s MHRP’s threat assessment research informs policy development and public health practices to decrease the rates of HIV and other STIs in the military.
- » WRAIR’s HIV Diagnostic and Reference Laboratory (HDRL) conducts state-of-art HIV screening and supplemental confirmatory testing, clinical and therapeutic monitoring services for U.S. military personnel.

## POTENTIAL TARGET IDENTIFIED: THREE NEUTRALIZING ANTIBODY LINEAGES

Three neutralizing antibody lineages were identified in an HIV-infected individual, insights which may help inform vaccine design. Researchers analyzed longitudinal samples from an HIV-infected individual who was part of WRAIR’s Military HIV Research Program (MHRP)’s RV217 acute infection cohort, a multi-site study led by MHRP in East Africa that has captured samples from some of the earliest stages of HIV infection. Antibodies in this individual targeted the membrane-proximal external region (MPER) of the HIV-1 envelope, a site of vulnerability that may hold promise as a potential HIV vaccine target. The findings were published in the journal *Immunity*.

## TOWARD A FUNCTIONAL CURE: ANTIBODY PROLONGED TIME TO HIV VIRAL REBOUND

Infusion of a broadly neutralizing antibody (bNAb) in virally suppressed, early treated volunteers was associated with a modestly delayed rebound of HIV after interruption of antiretroviral therapy (ART). The study, the first randomized controlled trial to demonstrate this effect of VRC01, was led by the MHRP and the Thai Red Cross AIDS Research Centre. The study is part of a portfolio of MHRP’s HIV remission research that seeks to find treatments to suppress the virus without a need for lifelong ART. Researchers evaluated the use of VRC01 in a small cohort of Thai men (RV254) who were diagnosed and initiated ART within the first month of HIV infection, and who had been virally suppressed for about three years. Results were published in the *Lancet HIV*.



## 65,000+ YOUNG WOMEN ENROLLED IN DREAMS INITIATIVES

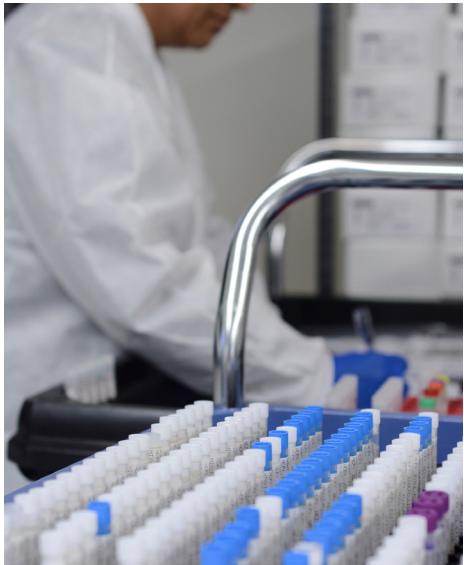
WRAIR’s MHRP’s partner sites in Uganda, Kenya and Tanzania have enrolled more than 65,000 young women in PEPFAR’s DREAMS public-partnership initiatives. This program aims to keep them Determined, Resilient, Empowered, AIDS-free, Mentored and Safe through education, vocational training and other evidence-based interventions. As of 2019, WRAIR’s MHRP and partners provide lifesaving antiretroviral treatment to more than 350,000 individuals with PEPFAR support.

## NEW CORRELATE IDENTIFIED

MHRP scientists identified a transcriptional signature in B cells associated with protection from SIV or HIV infection in five independent studies of HIV-1 vaccine candidates. The gene expression signature was found to correlate with protection in the only human HIV vaccine trial that previously showed modest efficacy, the WRAIR-led RV144. This new correlate of protection provides a clue as to why the vaccines were partially protective previously and may help to understand the mechanisms of efficacy in ongoing efficacy studies. Results were published in *Science Translational Medicine*.

## ALFQ VACCINE ADJUVANT AWARDED A PATENT

In the 1990s, MHRP at the Walter Reed Army Institute of Research developed a family of new adjuvants called the Army Liposome Formulation (ALF), and the ALFQ recently was awarded a patent. Adjuvants are vaccine components that help activate the immune system and improve immune responses. MHRP will be evaluating the effect of these promising new compounds on vaccine responses in various HIV vaccine clinical trials in Kenya and Thailand in 2020. It will also be tested with vaccines for malaria, enteric diseases and heroin.





# BATTLEFIELD RESILIENCE: FORGING SOCIAL COHESION

In multi-domain operations (MDOs), small teams are essential for mission performance. These teams must be able to sustain themselves in remote locations and function independently of larger units. To perform optimally, these teams, though disaggregated, must be characterized by a culture of support that offers a network of connection, essential for promoting resilience under difficult, arduous conditions.

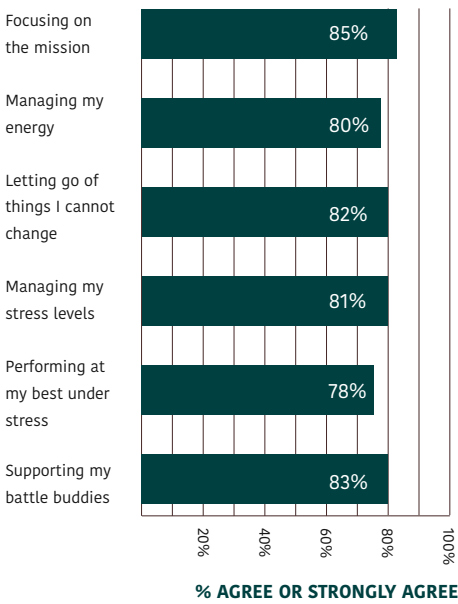


## ACE GATEKEEPER TRAINING

USAMRD-West, in collaboration with WRAIR-RTO, is evaluating the newly developed version of the ACE gatekeeper training (i.e., “ACE-SI”) for the Army Resilience Directorate. The goal of this training is to provide Soldiers with the knowledge and skills to temporarily intervene with Soldiers at risk for suicide until the Soldier can be connected to appropriate health resources. USAMRD-West’s researchers are coordinating closely with WRAIR-RTO and the Army Public Health Center (APHC). This effort highlights WRAIR’s continued engagement with emergent Army requirements, in support of Warfighter health and resilience.

## RESILIENCE ENHANCEMENT TRAINING FIELDIED

Soldiers need field-ready resilience tools that can help them manage the ongoing psychological demands of deployment. Partnering with the Army Resilience Directorate, WRAIR developed performance and resilience enhancement (PRE) skills for training at pre-deployment. Program evaluations of the training showed high acceptability among deploying Soldiers. Ratings from 286 Security Force Assistance Brigade Soldiers just before deploying to Afghanistan showed:

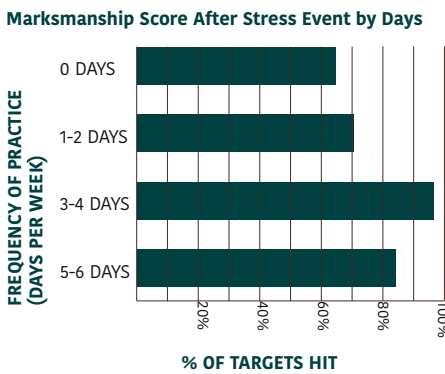


## MINDFULNESS IMPROVES HEALTH & OPERATIONAL OUTCOMES

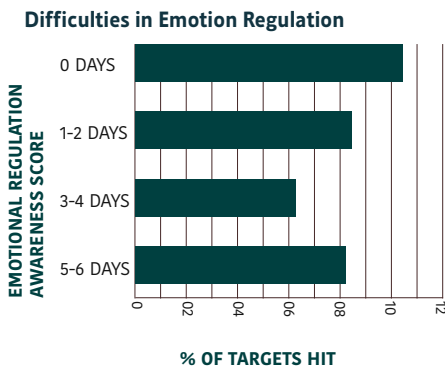


WRAIR’s Research Transition Office completed the first randomized trials to investigate the impact of mindfulness training on Soldier operational performance. The studies, funded by the Army Resilience Directorate, showed:

Soldiers practicing mindfulness on a regular basis scored 20% better on target accuracy



More practice was associated with fewer difficulties in regulating emotions



In response to the study findings, LTG Piatt, Director of Army Staff, directed SR2 to develop plans to roll out mindfulness training in selected TRADOC and FORSCOM units.

# BLAST, BRAIN INJURIES, AND NEUROPROTECTION

Since 2000, 383,947 Warfighters, mostly Soldiers, have been diagnosed with traumatic brain injury (TBI). Most are Army Soldiers. Causes for this injuries include: repetitive and acute blunt impact, repetitive and acute blast exposure, and acceleration/deceleration forces. Over 80 percent of these injuries have been diagnosed as “mild” TBI. Even though the majority of these injuries are classified as mild, early diagnosis and treatment is essential for optimal results. The quicker a Warfighter is diagnosed and treated, the quicker they recover.

In future multi-domain operations (MDO), Warfighters must be able to acquire, understand, synthesize, and convert into new information into real-time decision-making. Lack of air superiority and control in the warfare with near-peer adversaries may increase casualties from polytrauma (including brain injuries). Second only to hemorrhage, severe penetrating TBI represents our most significant debilitating and life-threatening trauma. Military planning for future multi-domain battlefields project higher numbers of trauma casualties with greater injury severities in an environment where direct support or medical evacuation may not be available for extended periods of time.

Efficient countermeasures, therapeutic and prevention with personal protective equipment, would Warfighters lethality that is directly relevant to MDO-2028 doctrine. In addition, successful Warfighters need to be at their cognitive, physical, and emotional peak. Unfortunately the consequences of TBI, although unique to the individual, include symptoms that may hinder or prevent a Warfighter from reaching their optimal performance, namely, headaches, dizziness, fatigue, degraded cognitive performance, and difficulty sleeping. Thus, innovative in-theater solutions are needed to promptly diagnose, treat, and return Warfighters to peak performance.



## CHRONIC NEUROBEHAVIORAL EFFECTS OF BLAST EXPOSURE

Blast-Induced Neurotrauma Branch researchers published the first study showing the chronic neurobehavioral effects of blast exposure from day 1 to 12 months post-blast in an experimental animal model (doi: 10.1089/neu.2019.6591). They documented acute changes in neurobehavioral functions followed by a recovery during sub-acute stages and subsequent significant deficits at 6 and 12 months, comparable to the changes observed in blast exposed victims. Understanding the primary and secondary neuropathological mechanisms responsible for changes in neurobehavioral functions will results in effective countermeasures.

## MORE OPPORTUNITY FOR TBI THERAPEUTIC INTERVENTIONS

Brain Trauma Neuroprotection Branch demonstrated that there are two phases of post-injury responses to mitochondrial bioenergetics failure in the brain--failure at the injury core region followed by delayed bioenergetics failure in the distal region from the injury. These findings identified a wider window of opportunity for therapeutic interventions targeting mitochondrial dysfunction after TBI, and suggest an extended drug therapeutics be necessary to achieve long-term efficacy.

## MRDC'S FIRST TRANSITION RESPONSE TEAM (TRT)

The Research Transition Office stood up MRDC’s first Transition Response Team (TRT) in partnership with the the U.S. Army Medical Materiel Development Activity. The TRT deployed to the USCENTCOM area of responsibility in March, 2019, to gather feedback at eight bases in Kuwait, Afghanistan, and Iraq on the feasibility and effectiveness of two TBI-detection devices under consideration for wide-spread fielding. The results from the TRT enabled the Army Surgeon General, the USCENTCOM Command Surgeon, and the Joint Staff Surgeon to provide the best military medical guidance to senior military and congressional leaders on the far-forward utility of current TBI-detection devices.





# FAR-FORWARD BEHAVIORAL HEALTH

Combat exposure is a robust predictor of mental health problems in U.S. Soldiers. PTSD with severe functional impairment prevalence estimates range from 8.5% to 14.1%, and up to 30% with some functional impairment (Thomas et al., 2010). The number of Soldiers experiencing acute or chronic stress-related symptoms related to combat operations is not clearly defined, but certainly greater than those meeting diagnostic criteria for PTSD (underreporting of symptoms is common due to stigma and career concerns). Data from Mental Health Advisory Teams, WRAIR-led efforts to embed mental health professionals within deployed units to gather behavioral health data for unit Commanders, show almost 50% of Soldiers report experiencing a unit member unable to function due to stress.

Evacuation for mental health problems accounted for nearly a quarter of all medical evacuations (CENTOM, AFHSB, 2017 and 2018), only behind musculoskeletal injury. The loss in force readiness and strength is significant. For instance, those evacuated for mental health reasons are four times more likely to separate from service (Peterson, Hale, 2018, Mil Med). Finally, the annual cost for treatment for post-traumatic stress-related symptoms in Veteran's is as high as 3 billion dollars (Institute of Medicine, 2017).

The nature of the war and the battlefield are anticipated to change to a multi-domain operations (MDO), and the research has to shift to meet this change. The MDO will be characterized by low density teams dispersed in austere environments with limited communications, a dearth of professional medical support, and an inability for immediate evacuation. Concurrent physical, cognitive, and emotional demands on Soldiers will be greater than before, increasing vulnerability for stress-related difficulties and acute and significant reductions in Force readiness and lethality. Immediate and rapid solutions will be required to keep Soldiers in the fight and minimize the impact of stress on cognitive, emotional, and physical function.

## BEHAVIORAL HEALTH READINESS (BHR) DECISION SUPPORT TOOLS

The Military Psychiatry Branch developed two behavioral health readiness (BHR) decision support tools and associated training which provides guidance on the BHR decision-making process, the overall military profile system and associated regulations, and a real-time check on clinical decision-making processes and skills, augmenting clinical judgment. The BHR decision support tools will help inform readiness for return to duty from psychological injury. Data in support of the study were evaluated at five sites with over 300 behavioral health providers trained in conjunction with the Office of the Surgeon General. These tools are expected to be transitioned in 2020.

## PTSD BLOOD BIOMARKERS SCREENING TOOL

WRAIR's Medical Readiness Systems Biology Branch completed a blood biomarker screening companion tool for post-traumatic stress disorder (PTSD) to objectively detect possible PTSD and/or subgroup characteristics of PTSD. This screen could have implications for the far-forward setting as well as during periodic health assessments for personnel exposed to traumatic experiences. The screening tool will provide support for soldier's readiness through objective detection, and will reduce the bias accompanying underreporting of symptoms the conventional screening solutions. An article was featured on Military times relating to this study that was recently published in the *Journal of Molecular Psychiatry*.



# WARFIGHTER FATIGUE MANAGEMENT

The sleep research team (SRT) has been developing novel interventions for the past decades. WRAIR developed the first actigraph that is now worn on the wrists of most Americans. We developed the SAFE-T model now utilized by the commercial airline industry to regulate the sleep and wake schedule for pilots and crews. WRAIR continues to be at the cutting edge, developing personalized, machine learning optimized strategies to individualize recommendations for sleep and caffeine intake. Recommendations for improving sleep in the general population are often inappropriate for military personnel in high OPTEMPO operational environments. WRAIR's SRT continues to develop and transition solutions for the unique and increasingly complex military operational environment.

## TRANSCRANIAL ELECTRICAL STIMULATION (tES) SLOWS PERFORMANCE DECLINES DURING SLEEP DEPRIVATION

WRAIR's researchers were able to show that tES applied during a two hour sleep opportunity slowed performance declines in a subsequent 46 hours total sleep deprivation challenge and helped individuals return to baseline faster during recovery. The purpose of this study was to determine if the enhancement of electroencephalographic (EEG) slow-wave activity using transcranial electrical stimulation (tES) at Slow Oscillation (SO) frequency, during a restricted period of nocturnal sleep, enhances the restorative properties of that period of sleep and improves performance during a subsequent period of sleep deprivation.

## 7ID WARFIGHTER FATIGUE MANAGEMENT TOOLS

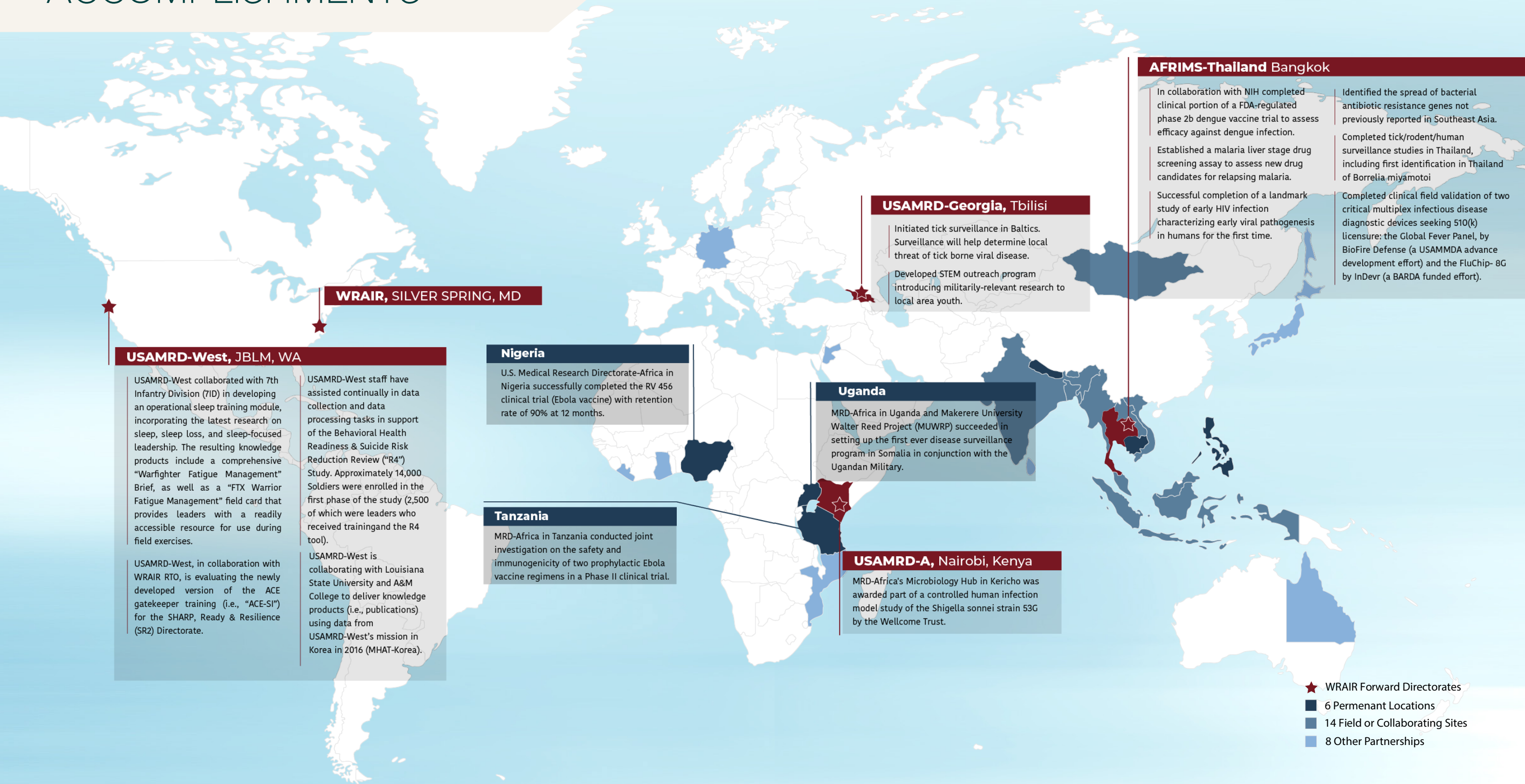
USAMRD-West collaborated with 7th Infantry Division (7ID) to developing an operational sleep training module, incorporating the latest research on sleep, sleep loss, and sleep-focused leadership. The module is targeted to company-, battalion-, and brigade-level leaders within the Division and addresses relevant operational sleep tactics and integration of sleep planning into field operations. The resulting knowledge products include a comprehensive "Warfighter Fatigue Management" Brief, as well as a "FTX Warrior Fatigue Management" field card that provides leaders with a readily-accessible resource for use during field exercises. These products highlight WRAIR's continued relevance to the operational force.

## TRANSITIONED THE 2B-ALERT PERFORMANCE MODEL

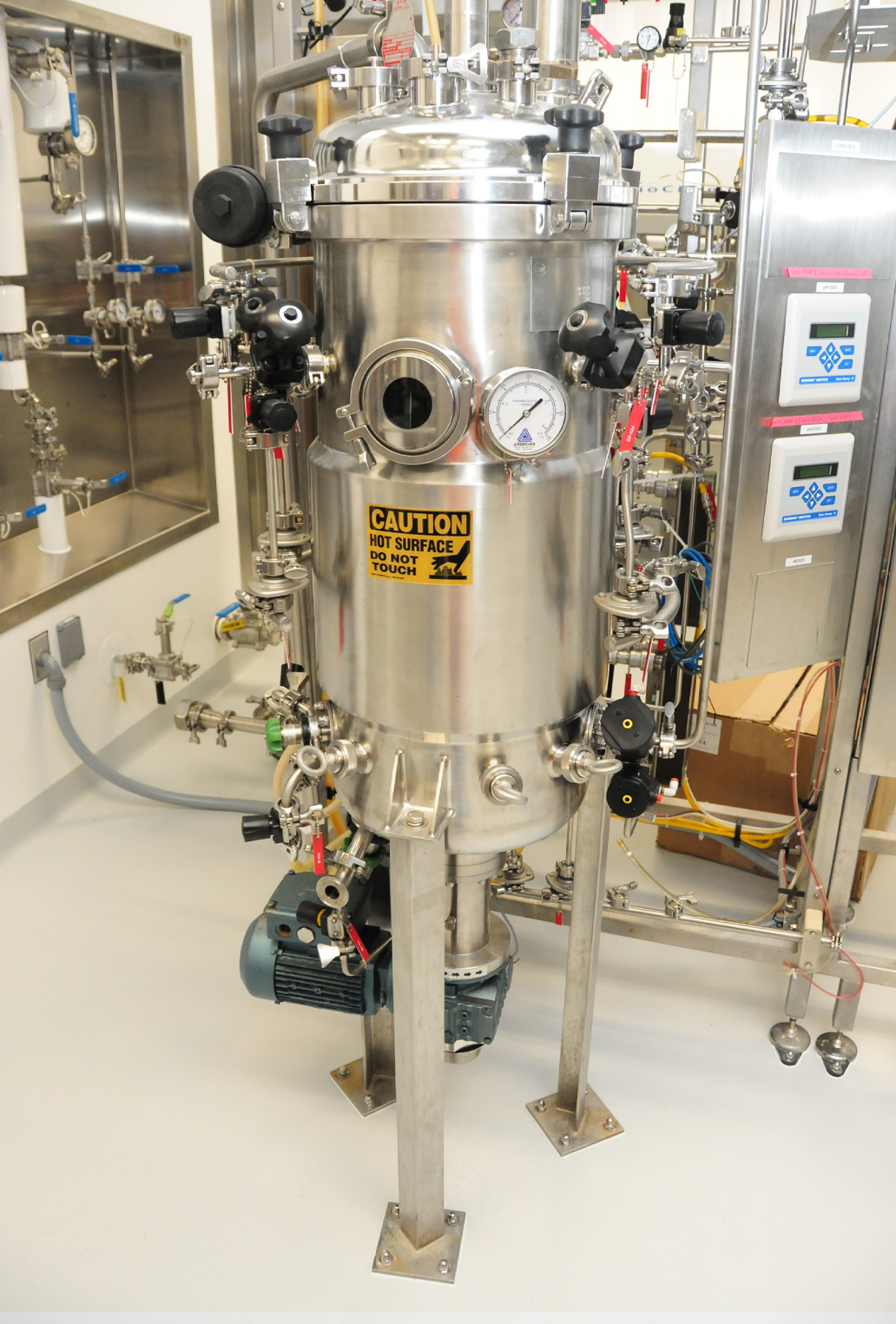
WRAIR transitioned the 2B-Alert performance model to the U.S. Army Medical Materiel Development Activity. 2B-Alert is the world's only performance prediction model that individualizes wakefulness with dosage and timing for optimal caffeine use. The Sleep Research Center worked in concert with Biotechnology High Performance Computing Software Applications Institute (BHSAI) to develop and refine this model which was recently non-exclusively licensed to an Australian company, Integrated Safety Support, through assistance of the USAMRDC Office of Medical Technology Transfer. Assessing Soldier fatigue in real time and providing recommendations to improve performance provides meaningful improvements to split-second decision making, learning and other skills vital to adequate function in a high-stress multi-domain environment; additionally, in far-forward settings with limited resupply, it can help conserve limited resources for use when they are truly needed.



# WRAIR-FORWARD LAB ACCOMPLISHMENTS







# THE BUSINESS OF SCIENCE

## PILOT BIOPRODUCTION FACILITY

WRAIR's Pilot Bioproduction Facility (PBF), a small good manufacturing practices-compliant manufacturing facility for vaccines and biologics, completed a full renovation in 2019; managed by the Army Corps of Engineers, the renovation brought the PBF to modern standards and dramatically expanded production capability. Capable of supporting pre-clinical and early-stage clinical testing, the PBF can also meet a DOD-wide need and serve as a critical part of a nationwide response to provide durable solutions to infectious disease. The facility is expected to be fully online midway through 2020.

## PILOT BIOPRODUCTION FACILITY VIALS PHAGE

WRAIR Pilot-Bioproduction Facility (PBF) helped prepare bacteriophage therapeutic cocktail as experimental treatment against multidrug resistant *P. aeruginosa* infection to be used under an emergency IND. Despite not being fully up and running in GMP mode yet, the PBF filled 100 vials of *P. aeruginosa* mixture for use in an e-IND. This material is intended to initially be administered to a patient with a deep *P. aeruginosa* infection in a leg wound that is not responding to antibiotic treatment. If it works, it will save amputation of the affected leg. The PBF was able to turn this around from a request for vials and stoppers to a full process, complete with significant cGMP documentation and methodology in less than two weeks, even though the facility is not yet ready for full cGMP production. There is reason to believe that, if this is successful, the PBF can help with other phage mixtures in the future.

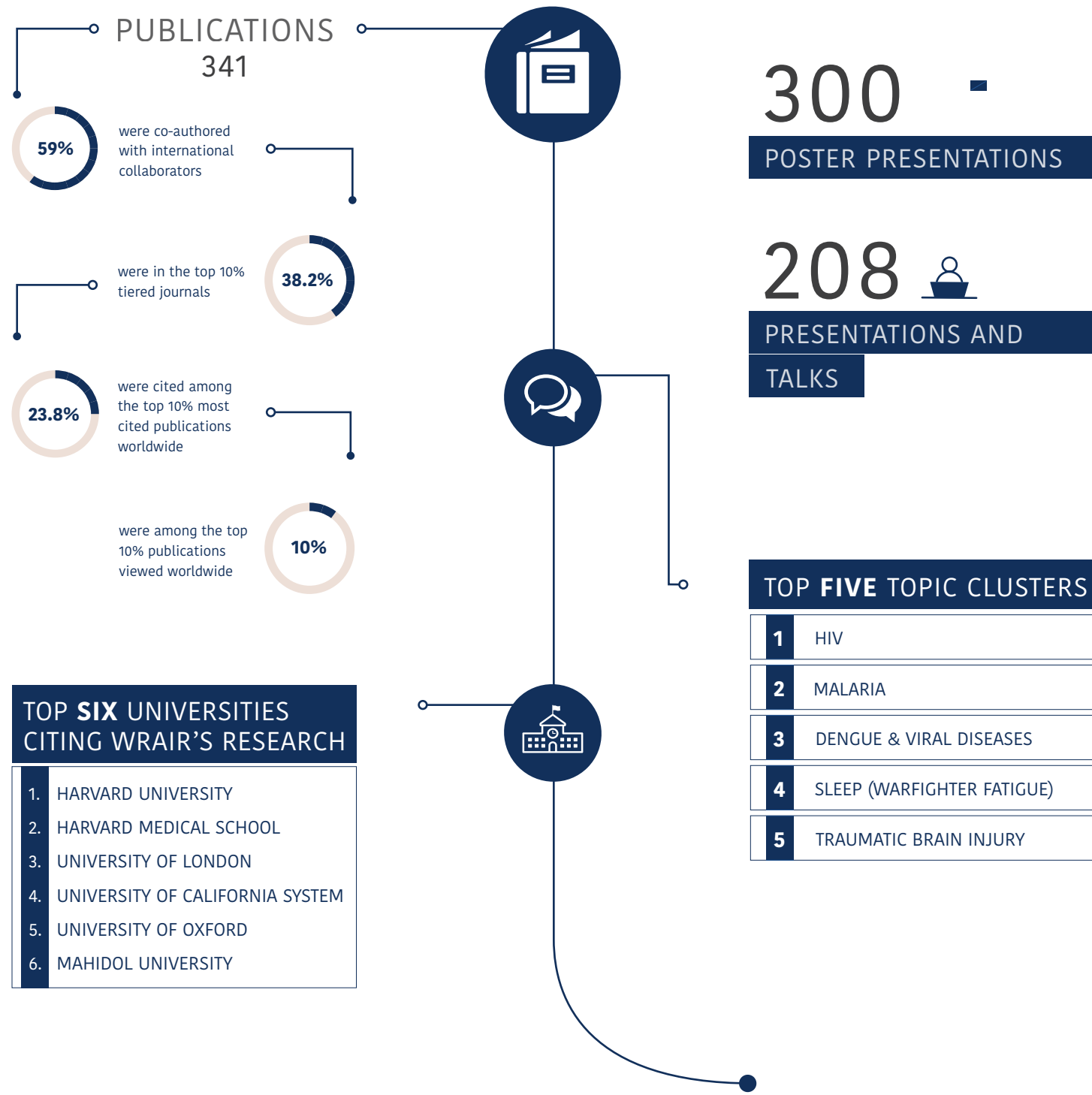


## CLINICAL TRIALS CENTER ACCOMPLISHMENTS

- 1 | CTC validated a new lot of malaria parasites to be used for malaria challenge trials throughout the world for the next 30 years. This trial will allow for replacement of the old lot of which nearly all the vials had been expended. This trial also generated the first clinical data for WRAIR's new PCR capabilities that can be used to modernize WRAIR's malaria challenge trials.
- 2 | CTC completed a first-in-human trial with the VLP malaria vaccine in collaboration with VLP therapeutics. This challenge trial was done to test the efficacy of a vaccine that uses an alphavirus particle to demonstrate malaria antigens which had the potential to protect against the malaria parasite and the alphavirus the VLP is derived from.
- 3 | CTC is starting a first-in-human trial in collaboration with Sanofi for an urgently needed improvement to one of the world's most successful vaccines. The yellow fever vaccine, developed in the 1930s, generates an excellent long-term immune response. However, the vaccine must be incubated/developed in chicken embryos which leads to production bottlenecks that have caused stock piles to be depleted during the last two outbreaks. The new vaccine is based on the original vaccine and has performed similarly in preclinical testing; this vaccine is produced in Vero cells which allow a much greater increase in production capability. Given the ongoing need and similarity to the predicate vaccine, very rapid development is anticipated for this first-in-human trial to move to FDA approval.
- 4 | The WRAIR CTC, in collaboration with scientists at the NIH's Vaccine Research Center, finished a critical first in human Marburg vaccine clinical trial in 2019. This Marburg vaccine used a novel strategy involving a replication-deficient recombinant chimpanzee adenoviral vector in combination with a portion of the Marburg viral glycoprotein. Marburg disease is similar to Ebola in its clinical symptoms, and its mortality rate may even be higher. This important vaccine's development timeline was accelerated in part due to the 2017 outbreak in Uganda where five people were infected and three died; ongoing Marburg outbreaks intermittently affect sub-Saharan Africa and threaten global health security. A similar Ebola vaccine developed by the VRC was tested in 2016-2017 and determined to be safe and immunogenic.



# WRAIR'S CY2019 PUBLICATIONS



## JOURNAL ARTICLES OF 2019

### Journal Articles Ranked By Impact Factor

	Journal	Impact factor
Lacerda, M.V.G., Llanos-Cuentas, A., Krudsood, S. et al. (2019). Single-dose tafenoquine to prevent relapse of plasmodium vivax malaria. New England Journal of Medicine, 380(3) 215-228	The New England journal of Medicine	70.67
Biswal S, Reynales H, Saez-Llorens X, Lopez P, Borja-Tabora C, Kosalaraksa P, et al. Efficacy journal of medicine. 2019;381(21):2009-19.	The New England journal of Medicine	70.67
Huestis DL, Dao A, Diallo M, Sanogo ZL, Samake D, Yaro AS, et al. Windborne long-distance migration of malaria mosquitoes in the Sahel. Nature. 2019;574:404-8.	Nature	43.07
Amambua-Ngwa A, Amenga-Etego L, Kamau E, Amato R, Ghansah A, Golassa L, et al. Major subpopulations of Plasmodium falciparum in sub-Saharan Africa. Science (New York, NY). 2019;365(6455):813-6.	Science	41.063
Yelin I, Flett KB, Merakou C, Mehrotra P, Stam J, Snesrud E, et al. Genomic and epidemiological evidence of bacterial transmission from probiotic capsule to blood in ICU patients. Nature medicine. 2019;25(11):1728-32.	Nature Medicine	30.641
Tinto H, Otieno W, Gesase S, Sorgho H, Otieno L, Liheluka E, et al. Long-term incidence of severe malaria following RTS,S/AS01 vaccination in children and infants in Africa: an open-label 3-year extension study of a phase 3 randomised controlled trial. The Lancet Infectious diseases. 2019;19(8):821-32.	The Lancet Infectious diseases	27.516
JModjarrad K, Roberts CC, Mills KT, Castellano AR, Paolino K, Muthumani K, et al. Safety and immunogenicity of an anti-Middle East respiratory syndrome coronavirus DNA vaccine: a phase 1, open-label, single-arm, dose-escalation trial. The Lancet Infectious diseases. 2019;19(9):1013-22.	The Lancet Infectious diseases	27.516
Kulkarni S, Lied A, Kulkarni V, Rucevic M, Martin MP, Walker-Sperling V, et al. CCR5AS lncRNA variation differentially regulates CCR5, influencing HIV disease outcome. Nature immunology. 2019;20(7):824-34.	Nature Immunology	25.53
Kanekiyo M, Joyce MG, Gillespie RA, Gallagher JR, Andrews SF, Yassine HM, et al. Author Correction: Mosaic nanoparticle display of diverse influenza virus hemagglutinins elicits broad B cell responses. Nature immunology. 2019;20(6):765.	Nature Immunology	25.53
Krebs SJ, Kwon YD, Schramm CA, Law WH, Donofrio G, Zhou KH, et al. Longitudinal analysis reveals early development of three MPER-directed neutralizing antibody lineages from an HIV-1-infected individual. Immunity. 2019;50(3):677-91.e13.	Nature Immunology	23.53



# JOURNAL ARTICLES OF 2019

1. Adney DR, Wang L, van Doremalen N, Shi W, Zhang Y, Kong WP, et al. Efficacy of an adjuvanted Middle East respiratory syndrome coronavirus spike protein vaccine in dromedary camels and alpacas. *Viruses*. 2019;11(3).
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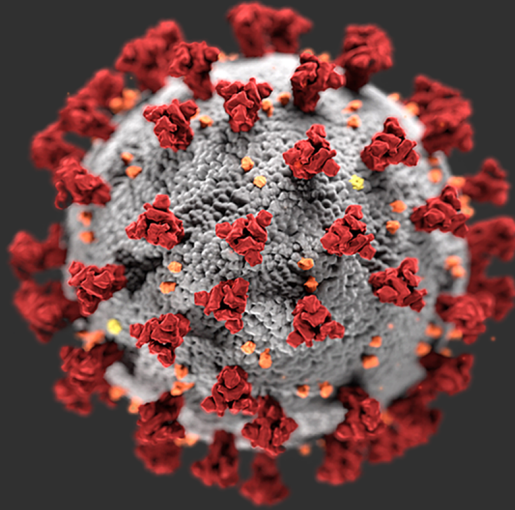


# COVID-19



## OVERVIEW

COVID-19 threatens political and economic stability, overwhelms capacity, and jeopardizes a calibrated force posture and the homeland. WRAIR is part of the U.S. Army Medical Research and Development Command's efforts to detect, prevent and treat covid-19 infection.



## COVID-19 SPREAD IN FOUR MONTHS



## WHAT IS IT?

COVID-19 is an illness caused by a coronavirus. COVID-19 has not been previously identified in humans. At this time, there are no specific vaccines or treatments for COVID-19.

## WHAT WE'RE DOING ABOUT IT



### PREVENT:

Creating a safe, efficacious vaccine and monoclonal antibodies



### DETECT:

Developing new tests for existing platforms in small, medium and large treatment facilities as well as the field to increase throughput and capacity



### TREAT:

Identifying, advancing, and gaining access to novel and existing antiviral drugs

## USAMRDC'S CAPABILITIES



### DISEASE SURVEILLANCE

WRAIR's laboratories on three continents and USAMRIID's deployable Center for Genomic Surveillance work to identify emerging infectious disease threats



### DISCOVERY

WRAIR and USAMRIID have the capabilities and experience to develop vaccines, treatment and prevention drugs, monoclonal antibodies, and diagnostics



### MANUFACTURING

WRAIR's newly renovated Pilot Bioproduction Facility can manufacture vaccines and biologics to support pre-clinical and early clinical testing



### PRE-CLINICAL

USAMRIID and WRAIR begin testing novel products in animal models to forecast safety and efficacy prior to any human exposure



### CLINICAL

WRAIR and USAMRIID operate clinical trial centers to perform early-stage clinical trials to test novel countermeasures



### DELIVERY

Product managers at USAMMDA work with the laboratories and user community to guide medical product development and acquisition while ensuring Warfighter relevance